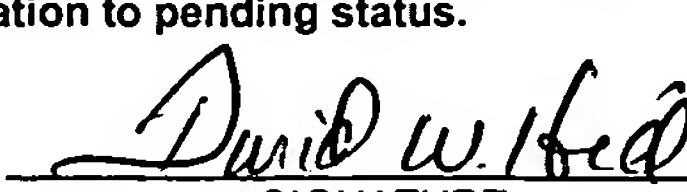


| | | |
|---|---|---|
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | CUSTOMER NO. 22,852 ATTORNEY'S DOCKET NUMBER: 03327.2355 U.S. APPLICATION NO. (If known, see 37 CFR 1.5) Not Yet Assigned |
| INTERNATIONAL APPLICATION NO. PCT/JP2005/002946 | INTERNATIONAL FILING DATE February 17, 2005 | PRIORITY DATE CLAIMED February 20, 2004 |
| TITLE OF INVENTION <p style="text-align: center;">PROPHYLACTIC ANTIMIGRAINE AGENTS</p> | | |
| APPLICANT(S) FOR DO/EO/US <p style="text-align: center;">Shinobu AKUZAWA and Toshihiro WATANABE</p> | | |
| Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)). <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed with the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)). <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). | | |
| Items 11 to 20 below concern document(s) or information included: | | |
| <ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> Information Disclosure Statement under 37 CFR 1.97 and 1.98 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A Substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154 (d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4). 20. <input checked="" type="checkbox"/> Other items or information: <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> International Search Report from the Japanese Patent Office b. <input type="checkbox"/> c. <input type="checkbox"/> d. <input type="checkbox"/> e. <input type="checkbox"/> | | |

| | | | | | |
|---|--------------|---|--|---|--------------|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) Not Yet Assigned | | INTERNATIONAL APPLICATION NO. PCT/JP2005/002946 | | ATTORNEY'S DOCKET NUMBER 03327.2355 | |
| The following fees have been submitted: | | | | CALCULATIONS | PTO Use Only |
| 21. <input type="checkbox"/> BASIC NATIONAL FEE (37 CFR 1.492(a)): | | | | \$ | |
| 22. <input type="checkbox"/> Examination fee (37CFR 1.492(c)) | | | | | |
| If the Written opinion prepared by ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 | | | | | |
| All other situations \$200 | | | | \$ | |
| 23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) | | | | | |
| If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 | | | | | |
| Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 | | | | | |
| International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 | | | | | |
| All other situations \$500 | | | | \$ | |
| TOTAL of 21, 22 and 23 = | | | | \$ | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | Rate | | |
| 63 - 100 = | 0 /50= | | x \$250.00 | \$ | |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | | | \$ | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total Claims | 10 - 20 = | 0 | x \$50.00 | \$ | |
| Independent Claims | 7 -3 = | 4 | x \$200.00 | \$ | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | + \$360.00 | \$ | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | | \$ | |
| SUBTOTAL = | | | | \$ | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest priority date (37 CFR 1.492(i)). | | | | + | \$ |
| TOTAL NATIONAL FEE = | | | | \$ | |
| Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property. | | | | + | \$ |
| TOTAL FEES ENCLOSED = | | | | \$ | |
| | | | | Amount to be refunded: | \$ |
| | | | | charged: | \$ |
| a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$_____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-0916</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 901 New York Avenue, N.W. Washington, DC 20001-4413 | | | | | |
| DATED: September 6, 2006 | | |  _____ SIGNATURE David W. Hill, Reg. No. 28,220 _____ NAME/REGISTRATION NUMBER | | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

National Phase of International Patent Application No.)
PCT/JP2005/002946)

Inventors:)
Shinobu AKUZAWA, et al.)

Application No.: **Not Yet Assigned**)

Filed: **August 18, 2006**)

For: **PROPHYLACTIC ANTIMIGRAINE AGENTS**)

MAIL STOP PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Sir:

Pursuant to 37 C.F.R. §§1.56 and 1.97(b), applicants bring to the Examiner's attention the documents listed on attached Form PTO/SB/08 and cited in the international search report. Copies of the listed non-U.S. patent documents are attached. Applicants respectfully request that the Examiner consider the documents listed on attached Form PTO/SB/08 and indicate that they were considered by making an appropriate notation on this form.

This Information Disclosure Statement is being filed within three months of the filing date of the above-referenced application.

In lieu of a statement of relevance or translation of the following non-English documents, enclosed is an English-language international search report from the Japanese Patent Office in corresponding international application number PCT/JP2005/002946 citing these references and setting forth the relevance thereof.

1. Japanese Patent Publication No. 11-506468 - This application corresponds to WIPO Publication No. WO 96/39382.

2. WIPO Publication No. WO 01/68585 A1 - An English-language abstract of this document is enclosed.


This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: September 6, 2006

By: 
David W. Hill
Reg. No. 28,220

Enclosures
DWH/FPD/tlm

| | | | | | |
|--|---|----|---|--------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | Not Yet Assigned |
| | | | | Filing Date | August 18, 2006 |
| | | | | First Named Inventor | Shinobu AKUZAWA |
| | | | | Art Unit | Not Yet Assigned |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | 03327.2355 |

| U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS | | | | | |
|---|-----------------------|--|---|---|---|
| Examiner Initials | Cite No. ¹ | Document Number | Issue or Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| | | US- 6,440,988 B1 | 08-27-2002 | CRAIG | |
| | | US- | | | |
| | | US- | | | |

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|--|---|--------------------------|
| Examiner Initials | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Translation ⁶ |
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | | WO 03/000252 A1 | 01-03-2003 | SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A. | | |
| | | JP 11-506468 | 06-08-1999 | FUJISAWA PHARMACEUTICAL CO., LTD. | | Abstract |
| | | WO 96/39382 | 12-12-1996 | FUJISAWA PHARMACEUTICAL CO., LTD. | | |
| | | WO 01/68585 A1 | 09-20-2001 | FUJISAWA PHARMACEUTICAL CO., LTD. | | Abstract |
| | | EP 1 264 820 A1 | 12-11-2002 | FUJISAWA PHARMACEUTICAL CO., LTD. | | |
| | | WO 2005/040169 A2 | 09-15-2004 | JANSSEN PHARMACEUTICA, N.V. | | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|--------------------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation ⁶ |
| | | D. W. BONHAUS, et al., "Cluster Headache and Related Conditions," vol. 9, (United Kingdom), Oxford University Press, 1999, pp. 278-286. | |
| | | K. SCHMUCK, et al., "Activation of Meningeal 5-HT _{2B} Receptors: An Early Step in the Generation of Migraine Headache?", European Journal of Neuroscience, vol. 8 (1996), pp. 959-967. | |
| | | J. A. TERRÓN, "Involvement of the 5-HT ₇ Receptor in Craniovascular Vasodilatation: Potential Impact in Migraine," Proc. West. Pharmacol. Soc., vol. 41 (1998), pp. 247-251. | |
| | | J. A. TERRÓN, "Is the 5-HT ₇ receptor involved in the pathogenesis and prophylactic treatment of migraine?", European Journal of Pharmacology, vol. 439 (2002), pp. 1-11. | |
| | | D. W. BONHAUS, et al., "RS-127445: a selective, high affinity, orally bioavailable 5-HT _{2B} receptor antagonist," British Journal of Pharmacology, vol. 127 (1999), pp. 1075-1082. | |
| | | P. J. LOVELL, et al., "A Noval, Potent, and Selective 5-HT ₇ Antagonist: (R)-3-(2-(2-(4-Methylpiperidin-1-yl)-ethyl)pyrrolidine-1-sulfonyl)phenol (SB-269970), J. Med. Chem., vol. 43 (2000), pp. 342-345. | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.